



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING  
VESSEL (4000 LITER)**

**DESIGN QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
SS JACKETED MANUFACTURING  
VESSEL**

<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



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VESSEL (4000 LITER)**

**PROTOCOL CONTENTS**

<b>S. No.</b>	<b>TITLE</b>	<b>PAGE No.</b>
<b>1.0</b>	<b>Protocol Pre-Approval</b>	<b>3</b>
<b>2.0</b>	<b>Objective</b>	<b>4</b>
<b>3.0</b>	<b>Scope</b>	<b>4</b>
<b>4.0</b>	<b>Responsibility</b>	<b>5</b>
<b>5.0</b>	<b>Project Requirements</b>	<b>6</b>
<b>6.0</b>	<b>Brief Equipment Description</b>	<b>6-7</b>
<b>7.0</b>	<b>Equipment Specification</b>	<b>9</b>
<b>8.0</b>	<b>Critical Variables To Be Met</b>	<b>9</b>
<b>8.1</b>	<b>Equipment Parameters</b>	<b>9</b>
<b>8.2</b>	<b>Utility Requirements / Location Suitability</b>	<b>10</b>
<b>8.3</b>	<b>Technical Specifications / Key Design Features</b>	<b>11-30</b>
<b>8.4</b>	<b>Material Of Construction</b>	<b>31</b>
<b>8.5</b>	<b>Safety</b>	<b>31</b>
<b>8.6</b>	<b>Vendor Selection</b>	<b>31</b>
<b>9.0</b>	<b>Documents To Be Attached</b>	<b>32</b>
<b>10.0</b>	<b>Review (Inclusive Of Follow Up Action, If Any )</b>	<b>32</b>
<b>11.0</b>	<b>Any Changes Made Against The Formally Agreed Parameters</b>	<b>32</b>
<b>12.0</b>	<b>Recommendation</b>	<b>32</b>
<b>13.0</b>	<b>Abbreviations</b>	<b>33-34</b>
<b>14.0</b>	<b>Reviewed By</b>	<b>35</b>



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

**1.0 PROTOCOL PRE- APPROVAL:**

**PREPARED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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**2.0 OBJECTIVE:**

- To prepare the Design Qualification on basis of User Requirement Specification, Purchase Order and information given by Supplier.
- To ensure that all Critical Aspects of Equipment / Product Requirement, cGMP and Safety have been considered in designing the Equipment and is properly documented.
- To specify the performance basis for acceptance of equipment.

**3.0 SCOPE:**

- The Scope of this Qualification Document is limited to the Design Qualification for SS jacketed Manufacturing tank (4000 ltr.) procured from **Pharmatech Process Equipment**.
- The Equipment shall operate under the Controlled Environmental Conditions as per the cGMP requirements.
- The drawings provided by Vendor shall be verified during Design Qualification.



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

**4.0 RESPONSIBILITY:**

The Validation Group, comprising of a representative from each of the following Departments, shall be responsible for the overall compliance of this Protocol cum Report:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Authorization and Compilation of Design Qualification Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.</li><li>• Co-ordination with Production and Engineering to carryout Design Qualification.</li><li>• Monitoring of Design Qualification activity.</li><li>• Review of Design Qualification Protocol cum Report after Execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review and Approval of Design Qualification Protocol cum Report.</li><li>• Assist in the verification of Critical Process Parameter, Drawings, as per the Specification.</li><li>• Review of Design Qualification Protocol cum Report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of Design Qualification Protocol cum Report.</li><li>• Assist in the Preparation of the Protocol cum Report.</li><li>• To co-ordinate and support the Activity.</li><li>• To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e.<ul style="list-style-type: none"><li>• GA Drawing</li><li>• Specification of the sub-components / bought out items, their Make, Model, Quantity and Backup Records / Brochures.</li><li>• Details of Utilities</li><li>• Identification of components for Calibration.</li><li>• Material of Construction of all components.</li><li>• Brief Equipment Description.</li><li>• Safety Features and Alarms.</li></ul></li><li>• Review of Design Qualification Protocol cum Report after Execution.</li></ul>



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

**5.0 PROJECT REQUIREMENTS:**

To confirm the safe delivery of the Equipment from the supplier Site. To ensure that no Unauthorized and / or Unrecorded design modification shall take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented.

The Compounding Vessel, its associated components and stirrer are designed to process pharmaceutical products in accordance with cGMP principles.

**6.0 BRIEF EQUIPMENT DESCRIPTION:**

Application: Jacketed (Limpeted) Manufacturing Vessel is used for Manufacturing of Pharmaceuticals product (LVP).

System Components

Jacketed (Limpeted) Manufacturing Vessel comprises of following parts.

- Shell

SS 316 L, Cylindrical, Vertical Shell, Top 10% Torispherical dish end & Bottom  
10% Torispherical dish end welded to shell

Inside Surface Finish: Ra H 0.5  $\mu\text{m}$ . Electro polish

- Limpet

SS 304, 4" NB x 3 mm Thick (Partial Limpet) @ 150 pitch Limpet coil.

- Insulation

38 mm Thick Armaflex insulation with 2 mm cladding on shell & 3 mm  
cladding on bottom cone. External surface finish: Ra H 0.9  $\mu\text{m}$ . Mechanical polish

- Stirrer

Kweng make bottom entry magnetic stirrer

- Supports

3 Nos. of SS-304 Leg Support on load cell

- Facility Devices

For vessel top

Spray ball

Sterile Safety valve

Compound gauge



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING  
VESSEL (4000 LITER)**

Rupture disc

Pneumatic operated (on/off) Diaphragm (PTFE with EPDM back up) valve for vent filter

Plain vent filter

Pneumatic operated (on/off) Diaphragm (PTFE with EPDM back up) valve for vent filter condensate

Temperature sensor with transmitter

Sterile steam trap

Piping & fittings

Halogen lamp

N<sub>2</sub> Sparger tube

Manual operated Diaphragm (PTFE with EPDM back up) valve for sparger

Manual operated Diaphragm (PTFE with EPDM back up) valve for CA/N<sub>2</sub> transfer

Manual operated Diaphragm (PTFE with EPDM back up) valve for WFI inlet

Manual operated Diaphragm (PTFE with EPDM back up) valve for CIP inlet at spray ball

Pneumatic operated (on/off) Diaphragm (PTFE with EPDM back up) valve for SIP at spray ball

Pressure sensor with transmitter

Dip Stick

For vessel bottom

Manual operated flush bottom Diaphragm (PTFE) valve with manual operated sampling valve

For shell side

Resterilizable Diaphragm (Platinum cured silicon) Sample valve

Pneumatic operated (on/off) Diaphragm (PTFE with EPDM back up) valve for SIP of sample valve

Manual operated Diaphragm (PTFE with EPDM back up) valve for sampling



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING  
VESSEL (4000 LITER)**

Temperature sensor with transmitter

Sterile steam trap

Piping & fittings

Temperature sensor with transmitter for vessel

For vessel limpet side

Pneumatic operated (on/off) Ball valve for steam inlet

Pneumatic operated (on/off) Ball valve for cooling water supply and return

Pneumatic operated (on/off) Ball valve for compressed air inlet

Safety valve for limpet

Pressure gauge for limpet

Pneumatic operated (on/off) Ball valve for limpet air vent

Auto steam trap unit

SS Braided hose pipe for utility

Other accessories

Load cell with IND 570 weight indicator

Variable Frequency drive

Pneumatic operated (on/off) Diaphragm (PTFE with EPDM back up) valve for  
SIP at drain

Manual operated diaphragm (PTFE with EPDM back up) valve for CIP drain

Temperature sensor with transmitter

Sterile steam trap

Piping & fittings

Conductivity Sensor with Analyzer

Flexible hose for common drain header

Flexible hose, 1000 mm long (loose supply)

SS 304 fixed skid





# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)

### 7.0 EQUIPMENT SPECIFICATION :

Equipment Specification is a document provided to Manufacturer as per the specifications mentioned in User Requirement Specification.

### 8.0 CRITICAL VARIABLES TO BE MET:

#### 8.1 EQUIPMENT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
<b>Application:</b> The purpose of manufacturing vessel is mixing of pharmaceutical product with magnetic stirrer.	Manufacturing vessel shall be <ul style="list-style-type: none"><li>• Able to dissolve the Solid content in the Solvent Media to provide solution</li><li>• Leak free</li><li>• Jacketed to control the temperature of the solution</li></ul>	Process Requirement
<b>Working</b>	Should work smoothly and should run without producing any unwanted sound.	Process Requirement
<b>Electrical Control Panel</b>	The system should have Electrical Control Panel.	Design Requirement



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

**8.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY :**

<b>CRITICAL VARIABLE</b>	<b>ACCEPTANCE CRITERIA</b>	<b>CONSUMPTION</b>
Electricity	3 Phase, 50 Hz, 415 VAC	4 HP
SIP Media	at 2 Bar(g)	21.6 Kg/ Cycle
CIP Media	at 2 Bar(g)	71 LPM
Cooling Water	35° C Max. @ 2 bar (g)	As per requirement
Compressed Air	@ 1.5 – 2 Bar(g)	As per requirement
Room Condition	Should be able to meet the	cGMP Requirement



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

**8.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:**

**8.3.1 Technical Specifications for Jacketed Manufacturing Vessel**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
<b>Equipment</b>	4000 Ltr. Jacketed Manufacturing Vessel		cGMP Requirement
<b>Sr. Number</b>	16- 17/ SJ/000564		cGMP Requirement
<b>Application</b>	Manufacturing of pharmaceuticals product		cGMP Requirement
<b>Hazard area</b>	Non – Flameproof		cGMP Requirement
<b>Design Code</b>	cGMP / ASME Guidelines		cGMP Requirement
<b>Density</b>	1000 Kg/M <sup>3</sup>		cGMP Requirement
<b>Viscosity</b>	200 cPs Max.		cGMP Requirement
<b>Volume</b>	Working Gross	4000 Ur. 4805 Ur.	cGMP Requirement
<b>Working condition</b>	Shell Jacket	-0.9 to 3 Bar(g) @ 5 to 135° 3 Bar(g) @ 5 to 150°	cGMP Requirement
<b>Design Condition</b>	Shell Jacket	-1 to 4 Bar(g) @ 0 to 150° 4 Bar(g) @ 0 to 180°	cGMP Requirement
<b>MOC</b>	Contact Non Contact Gasket	AISI S 316 L AISI SS 304 Food Grade Silicon	cGMP Requirement
<b>Surface Finish</b>	Internal External	Ra ≤ 0.5 µm Electro Polish Ra ≤ 0.9 µm Mechanical polish	cGMP Requirement
<b>Radiography</b>	Rectangle Shell	Nil 100%	cGMP Requirement
<b>Shell</b>	Shell Heads	Ø 1750 X 1500 X 6 mm thick Top 10 % Torispherical, 10 mm thick (Nom.) Bottom 10 % Torispherical, 10 mm thick (Nom.)	cGMP Requirement
<b>Limpet</b>	Shell  Pitch	4" NB x 3 mm Thick (Partial Limpet) 150mm	cGMP Requirement
<b>Insulation</b>	Type Thicknes s SS cladding	Armaflex 38 mm 2 mm thick SS cladding on shell & 3 mm thick SS cladding on	cGMP Requirement



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
Support	Type	3 Nos. SS 304 Legs support on load cell	cGMP Requirement
Support	Type	3 Nos. SS 304 Legs support on load cell	cGMP Requirement
Overall Size of vessel	Diameter Height	~ 1920 mm (ID) ~ 3320 mm (up to top of vent filter)	cGMP Requirement
Weight	Empty Full of Water	~1815 Kgs. ~6620 Kgs.	cGMP Requirement

**8.3.2 Bottom Entry Magnetic Stirrer:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
Magnetic stirrer	Type Mounting Rating RPM Sweep Diameter Model no. Make Quantity	Magnetic Stirrer Bottom (off Centre) 2.2 KW 50-350 220 mm BAGI 10K Kweng 1 No.	cGMP Requirement
Drive Unit	Motor Type Power Speed Mounting Power supply Make Quantity	Geared motor Non Flameproof Motor 2.2 KW 2880 RPM Flange 415 V AC, 50 Hz, 3 phase Bonfiglioli 1 No.1 No.2880 RPM Flange 415 V AC, 50 Hz, 3 phase Bonfiglioli 1 No.	cGMP Requirement



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
	Gear box Type Ratio Mounting Make Quantity	Worm type 7 : 1 Ratio Flange mounting Bonfiglioli 1 No.	

**8.3.3 Technical Specifications of Accessories & Bought-out Components:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
<b>Spray ball.</b>	Type MOC Size Mounting Water Flow End Connection Part No. Tag no.	Self rotating, 360° rotating, detachable SS 316 L Ø 61 On top 73 LPM @ 2 Bar(g) 3/4" BSP FEMALE 569-139-1Y-AL SB Qty : 1 Nos Make : Lecher	cGMP Requirement
<b>Sterile Safety valve</b>	Type MOC Size Mounting Capacity Set Press. Tag no. Make Qty.	Sterile Diaphragm Contact SS 316 L Diaphragm Silicon Non contact SS 304 Ø 9.3 x 12.5 mm (Inlet/Outlet) Ø 25 T/C 100 M3/Hr of Steam @ 2.5Barg and 60 M3/Hr of air 3.24 Bar(g) SSV  Pharmatech 1 Nos	cGMP Requirement



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
<b>Compound gauge</b>	Type MOC  Size Mounting Range Accuracy Tag no. Make Qty	Sterile Diaphragm Gauge Contact SS 316 L Non-Contact SS 304 4" Dial Ø 38 mm T/C end -760 mm Hg to 6 Bar(g) ± 1.6% FSD CG Baumer 1 Nos	cGMP Requirement
<b>Ruptured Disc</b>	MOC  Size End connection Burst pressure Tag no. Make Qty	Contact parts : SS 316L Gasket : PTFE 1.5" T/C Suitable for 50.5 mm OD T/C 3.5 kg/cm <sup>2</sup> @ 180 °C RD Fke 1Nos	cGMP Requirement
<b>Diaphragm valve for vent filter</b>	Type  Size MOC  End connection Make Qty.	Pneumatic operated (on/off) Diaphragm valve Dia. 38 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up T/C ended CV1, CV2 Gamu 1 Nos	cGMP Requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
<b>Plain Vent Filter</b>	Type Rating Size Filter Area MOC  Mounting Model  Make. Qty.	Emflon, code7, Hydrophobic 0.2 micron 10" Long ~0.29 M2 Housing SS 316L Cartridge Double Layer PTFE Gasket Silicon 25 mm T/C Cartridge: CTGR71TP1 Housing :  Millipore 1 Nos	cGMP Requirement
<b>Diaphragm valve for vent filter condensate</b>	Type  Size MOC  Make Qty.	Pneumatic operated (on/off) Diaphragm valve Dia. 12 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up  Gamu 1 Nos	cGMP Requirement
<b>Temperature sensor with transmitter for vent filer SIP line</b>	Type MOC Mounting Range Accuracy Sheath Diameter Length Output .Make Qty.	PT 100, RTD, 3 Wire Sensor SS316L Thermowell SS316L Mini T/C 0° to 200°C Class 'A' 8 mm Ø 65 Long 4-20 mA TS2 Radix 1 Nos	cGMP Requirement



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QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
<b>Sterile steam trap</b>	Type MOC  Size Steam trap Model Capacity Surface finish Sub cooling Max. Allow. Pressure Max. Allow. Temperature End Conn. Make Qty.	Bellows type thermostatic steam trap Body – SS 316L Thermal element – SS 316L 'O' ring – Teflon encapsulated Viton Ø 12 mm  Sterile flow – MK 93 249 LPH @ 2 Bar(g) Internally 0.5 Ra mech. Polish Approx. 5 °F  145 psig 350 °F Mini T/C ST1  Jordan 1 Nos	cGMP Requirement
<b>Halogen lamp</b>	Type  Power supply Consumption Mounting MOC Make. Qty.	Halogen lamp with bracket 230 V AC 50 W halogen On light glass Stainless steel  Papenmeire 1 Nos	cGMP Requirement
<b>N2 Sparger tube</b>	MOC Size End Connection  Make. Qty.	SS 316 L Sparger tube Dia. 12 mm T/C ended Pharmatech 1 Nos	cGMP Requirement





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QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
<b>Diaphragm valve for sparger tube</b>	Type Size MOC End connection Make Qty.	Manual operated Diaphragm valve Dia. 12 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up T/C ended MV4 Gamu 1 Nos	cGMP Requirement
<b>Diaphragm valve for CA/N<sub>2</sub></b>	Type Size MOC End connection Tag no. Make Qty.	Manual operated Diaphragm valve Dia. 25 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up T/C ended MV3 Gamu 1 Nos	cGMP Requirement
<b>Diaphragm valve for WFI inlet</b>	Type Size MOC End connection Tag no Make Qty.	Manual operated Diaphragm valve Dia. 38 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up T/C ended MV1 Gamu 1 Nos	cGMP Requirement
<b>Diaphragm valve for CIP inlet at Spray Ball</b>	Type Size MOC End connection Tag no Make Qty.	Manual operated Diaphragm valve Dia. 50 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up T/C ended MV2 Gamu 1 Nos	



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
<b>Diaphragm valve for SIP at Inlet at Spray Ball</b>	Type Size MOC  End connection Tag no  Make Qty.	Peumatic operated Diaphragm valve Dia. 38 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up T/C ended CV4  Gamu 1 Nos	
<b>Pressure Sensor with Transmitter</b>	Type  Housing  Output Pressure Range Process Connection  Response Time Protection Model No. Tag No. Make	D TRANS p31, 402050 Stainless Steel, Mat Ref. 1. 43301 Polycarbonate GF  4-20 ma, 2 Wire -1 to 5 Barg T/C Clamp  3msec Max IP65 to EN 60 529 43010260 PS- PT Jumo	Design Requirement
<b>Diaphragm valve for CIP drain</b>	Type  Size MOC  End connection Tag no.  Make Qty.	Manual operated Diaphragm valve Dia. 50 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up T/C ended  MV8  Gamu 1 Nos	cGMP Requirement



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
<b>Temperature Sensor with transmitter for vessel</b>	Type MOC  Mounting Range Accuracy Sheath Diameter Length Connection Output Tag no. Make Qty.	PT 100 RTD, 3 wire Thermo well SS 316L Sensor SS 316L 1 1/4" BSP 0° to 200°C Class 'A' 8 mm Ø 65 Long 3 Wire 4-20mA, 2 wire TS3 Radix 1 Nos	cGMP Requirement
<b>Sterile steam trap</b>	Type MOC  Size Steam trap Model Capacity Surface finish Sub cooling Max. Allow. Pressure Max. Allow. Temperature End Conn. Tag no.  Make Qty..	Bellows type thermostatic steam trap Body – SS 316L Thermal element – SS 316L 'O' ring – Teflon encapsulated Viton Ø 25 mm  Sterile flow – MK 93 249 LPH @ 2 Bar(g) Internally 0.5 Ra mech. Polish Approx. 5 °F  145 psig ST 2 350 °F Mini T/C ST2  Jordan 1 Nos	cGMP Requirement



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QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
<b>Restrilizable Sample Valve</b>	Type Size MOC End connection Make	Resterizable Sample Valve Dia. 12 mm  Contact Parts : SS 316 L Non Contact Parts : SS 304 Diaphragm : Platinum Curved Silicon  T/C ended Novaseptic	cGMP Requirement
<b>Diaphragm valve for SIP of Sampling Valve</b>	Type Size MOC End connection Tag no Make Qty.	Peumatic operated Diaphragm valve Dia. 12 mm Contact parts: SS 316L Non contact parts: SS 304 Diaphragm: PTFE with EPDM back up T/C ended CV14 , CV13 Gamu 1 Nos	cGMP Requirement
<b>Diaphragm Valve for sampling</b>	Type Size MOC End Connection Tag No. Make	Manual Operated Diaphragm Valve  Dia. 12 mm  Contact Parts : SS316L Non Contact Parts : SS304 Diaphragm PTFE with EPDM back up  T/C/ end MV8 Gemu	cGMP Requirement



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
<b>Temperature sensor with transmitter for sampling Valve SIP line</b>	Type MOC Mounting Make Qty  .Range Accuracy Sheath Diameter Length Output  Tag no.  <b>Make</b>	PT 100, RTD, 3 Wire Sensor SS316L Thermowell SS316L Mini T/C Radix 1 Nos 0° to 200°C Class 'A' 8 mm Ø 65 Long 4-20 mA TS4  Radix	cGMP Requirement
<b>Sterile steam trap</b>	Type MOC  Size Steam trap Model Capacity Surface finish Sub cooling Max. Allow. Pressure Max. Allow. Temperature End Conn. Tag no  Make Qty..	Bellows type thermostatic steam trap Body – SS 316L Thermal element – SS 316L 'O' ring – Teflon encapsulated Viton Ø 12 mm  Sterile flow – MK 93 249 LPH @ 2 Bar(g) Internally 0.5 Ra mech. Polish Approx. 5 °F  145 psig  ST 3 350 °F Mini T/C ST2 Jorden 1 Nos	cGMP Requirement



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**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
<b>Conductivity Sensor with Analyzer</b>	Series Cell Constant Measurement principal Body Temperature Device Accuracy of Cell Measuring Range  Insertion length  Connection Part. No.  Model Type Power Supply Current Output Display Mounted Part No. Tag No. Make	<u><b>Conductivity Sensor</b></u> Thortan 0.1 /cm 2- Electrode Sensor  SS 316 L Pt 1000 IEC Class A  ± 1% 0.02 to 3000 µS/Cm  85 mm  1.5 “ T/C Clamp 58031414 <u><b>Transmitter</b></u> M200 Single Chanel analyzer 110 to 240 V AC 4- 20 mA Backlit LCD, 4 Lines Panel Mounted 52121554 CS-CT Mettler Toledo	
<b>Dip Stick</b>	Type  MOC Size End Connection  Make	Dip Stick with Marking Contact Part – SS 316 L Non Contact SS304 25 W x 6 thk. Ø 38 mm TC end  Pharmatech	



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
<b>Safety Valve for Jacket</b>	Type	Conventional FLS-549 06/CS44 SS2	cGMP Requirement
	Model		
	MOC		
	Inlet Body	AISI316 L	
	Outlet Chamber	ASTM A 351 CF 8	
	Bonnet	ASTM A 351 CF 8	
	Trim	AISI 316 L	
	Disc Spring	AISI 316 L Stainless Steel	
	Gasket	PTFE	
	Inter Con. Rating		
	Outlet Connection		
	Rating	1'' BSP ( F)	
	Over Pressure	10 %	
	Set Pressure	3.24	
	Service	Steam	
	Temperature	150 ° C	
	Cap Type	Closed, H2	
	Make	Fainger Leser	
<b>Pressure Gauge for Jacket</b>	Type MOC	Bourden SS 304	cGMP Requirement
	Size Range	Ø 2.5'' Dial	
	Accuracy	0 to 7 Bar(g)	
	End connection	± 1% FSD 1/4'' BSP Threaded	
	Make	Baumer	
	Qty.	1 Nos	



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**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
<b>Ball valve for Air vent</b>	Type Size MOC End Connection Tag no. Make Qty	Pneumatic operated (on/off) Ball valve Dia. 12 mm SS 304 T/C ended CV5 Micro 1 Nos	cGMP Requirement
<b>Ball valve for Compressed air inlet</b>	Type Size MOC End Connection Tag no. Make Qty.	Pneumatic operated (on/off) Ball valve Dia. 12 mm SS 304 T/C ended CV8 Micro 1 Nos	cGMP Requirement
<b>Ball valve for Steam inlet</b>	Type Size MOC End Connection Tag no. Make Qty.	Pneumatic operated (on/off) Ball valve 40 NB SS 304 T/C end CV6 Micro 1 Nos	cGMP Requirement
<b>Ball valve for cooling water supply and return</b>	Type Size MOC End Connection Tag no. Make Qty.	Pneumatic operated (on/off) Ball valve Dia. 25 mm SS 304 T/C End CV7, CV9 Micro 1 Nos	cGMP Requirement





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<b>Steam Trap Unit</b>	Type MOC Size End connection  Make Qty.	<b>Steam Trap</b> Thermodynamic Body – SS 316 Strainer – SS 304 20 NB 3/4” BSP Threaded  Rex 1 nos	cGMP Requirement
	Type Size MOC End connection Tag no.  Make Qty.	<b>Valve</b> Pneumatic Operated Ball Valve 25 NB SS 304 T/C end CV10, CV11  Micro 2 nos	cGMP Requirement
	Type Size MOC End connection Tag no Make Qty.	<b>Piping</b> Dia. 38 mm ERW SS 304 T/C End Pharmatech 1 Nos	
<b>Flexible hose for utility</b>	Type Size MOC End connection  Make Qty.	SS Braided hose pipe, Dia. 25 mm, 500 mm long SS Braided T/C ended  Shanti 2 Nos	cGMP Requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA		REFERENCE
<b>Load Cell</b>	Model Max. Capacity of single load cell Readability System Accuracy MOC Indicator  Make Qty.	0745A -550 Kg load cell  2200 Kg 100 gm ± 0.05% of FSD SS 304 IND 570  Mettler Toledo 3 Nos	cGMP Requirement
<b>Variable Frequency Drive</b>	Series Rating Power supply Output Frequency Protection Ambient temp. Ambient humidity EMC Filter  Make Qty.	ACS550 3 HP 380-500 V AC +10%/-15%,3 ph 50 ... 60 Hz ±5% IP20 -10 to 55° C  max 95% non-condensing Inbuilt ABB 1 Nos	cGMP Requirement
<b>Flexible hose for common drain header</b>	Type  Size MOC End connection  Make Qty.	Platinum Cured SS Wire Silicon Braided Hose Dia. 63.5 mm, 1000 mm long Platinum cured silicon T/C ended  Amipolymer 1 Nos	cGMP Requirement
<b>Flexible hose (loose supply)</b>	Type  Size MOC End connection Make Qty.	Platinum Cured SS Wire Silicon Braided Hose Dia. 25 mm, 1000 mm long Platinum cured silicon T/C ended Amipolymer 1 Nos	cGMP Requirement



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<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>		<b>REFERENCE</b>
<b>Control Panel</b>	Type MOC Mounting Gasket Size Finish Size  Make Qty	Dust Proof SS 304 Suitable Rubber 1000 x 800 x 300  Rittal 1 Nos	cGMP Requirement
<b>PLC</b>	Type Model No. Power Supply  Make  Qty  Ports Software Oper. Temperature	Programmable Logic Controller ML-1400 24 VDC  Allen Bradley  1 Nos  Serial and Ethernet RS Logix 500	cGMP Requirement
<b>HMI</b>	Type Model No. Power Supply Inch Resolution Backlight Comm. Port Software Oper. Temperature Relative Humidity  Make qty	Color touch screen PVP-600 18-30VDC 5.7" 320X240, 18-bit color graphics CCFL, 50, 000H RS232, USB and Ethernet Port RS view Factory 0-55°C 5-95%  Allen Bradley 1 Nos	cGMP Requirement



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VESSEL (4000 LITER)**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>		<b>REFERENCE</b>
<b>Printer</b>	Type Model no Power supply Location  Communication Port Make Qty	Dot matrix/Online printer LX-310 + II 230 VAC, Single phase On SS printer stand  25Pin – RS 232  Epson  1 Nos	cGMP Requirement
<b>FRL Unit</b>	Model Range Mounting location]  Make Qty	FRC 1/4-D-MINI 0 -16 Bar  Panel Mounted  Festo 1 Nos	cGMP Requirement
<b>Buzzer</b>	Type Supply Make Qty	Panel Mounted 220 V Ozzo 1 Nos	cGMP Requirement



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING  
VESSEL (4000 LITER)**

**8.3.4 Nozzle Schedule:**

<b>Nozzle</b>	<b>SIZE</b>
M	Ø 450
N1	Ø 38
N2 A	Ø 76 X 25
N2 B	Ø 76 X 25
N4	Ø 38
N5	Ø 25
N6	Ø 38
N7	Ø 25
N8	Ø 38
N9	Ø 50 x Ø 12
N10	Ø 25
N11	Ø 38
N12	1 ¼" BSP
N13	1 ¼" BSP
N14	Ø 12
N15	50 NB
N16	50 NB
N17	Ø 19
N18	Ø 12
N19	Ø 19
N20	Ø 38



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**8.4 MATERIAL OF CONSTRUCTION**

S. No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Vessel shell	SS316L
2.	Jacket shell	SS 304
3.	legs	SS 304
4.	Manhole gasket	Food Grade Silicon
5.	Insulation	SS 304
6.	Spray ball	SS 316L
7.	Rupture Disk	SS 316L
8.	Safety valve	SS 316L
9.	Compound Gauge	SS316 L
10.	Pressure gauge for jacket	SS316 L
11.	Manual Ball Valve	SS304
12.	Steam Trap unit	SS316 L
13.	SS Skid	SS304
14.	Control Panel	SS304
15.	Contact part	SS316 L
16.	Non Contact part	SS304

**8.5 SAFETY:**

SAFETY DEVICE	SPECIFIED FUNCTION	REFERENCE
SS Cover on Drive unit	For operator safety	Safety Requirement
Variable Frequency Drive	Motor safety from overload	Safety Requirement
Safety valve	Safety against pressure	Safety Requirement
Rupture Disc	Safety against Over pressure	Safety Requirement
Earthing boss	Reducing risk from shock	Safety Requirement



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<b>SAFETY DEVICE</b>	<b>SPECIFIED FUNCTION</b>	<b>REFERENCE</b>
Insulation	For operator safety & Heat loss prevention	Safety Requirement
Emergency Button	Protection against abnormal condition	Safety Requirement
Instruments air pressure switch	Low air pressure protection	Safety Requirement

**8.6 VENDOR SELECTION:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Selection of Vendor for Manufacturing vessel.	Selection of Vendor is done on the basis of review of vendor. Criteria for review includes Vendor Background (General / Financial), Technical know-how, Quality Standards, Inspection of Site, Costing, feedback from Market .	cGMP Requirement

**Reference:** Design & Functional Specifications provided by Vendor.

**Checked By**  
**(Engineering)**  
**Sign/Date:**.....

**Verified By**  
**(Quality Assurance)**  
**Sign/Date:** .....

**Inference:**

.....

.....

.....

.....

.....

**Reviewed By**  
**(Manager QA)**  
**Sign/Date:**.....



**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

**9.0 DOCUMENTS TO BE ATTACHED:**

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Any other relevant Documents

**10.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):**

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**11.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:**

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**12.0 RECOMMENDATION:**

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**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING VESSEL (4000 LITER)**

**13.0 ABBREVIATIONS:**

AC	:	Alternate current
ASA	:	American Standard Association
ASME	:	American Society for Mechanical Engineers
BSP	:	British Standard Pipe
cGMP	:	Current Good Manufacturing Practices
CIP	:	Clean in Place
db	:	Decible
DIN	:	Deutsches Institut for Normuung
DQ	:	Design Qualification
EPDM	:	Ethylene Propylene Dyne monomer
FAT	:	Factory Acceptance Test
GA	:	General Arrangement
HMI	:	Human Machine Interface
HP	:	Horse Power
Hz	:	Hertz
JMV	:	Jacketed Manufacturing Vessel
KGS	:	Kilograms
KW	:	Kilo Watt
LPM	:	liter per Minute
Ltd.	:	limited
MFT	:	Manufacturing Vessel
mm	:	Millimeter
MOC	:	Material of Construction
NO	:	Number
O.D.	:	Outside Diameter
PG	:	Pressure Gauge
PLC	:	Programmable Logic Controller
PO	:	Purchase Order



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PTFE	:	Poly Tetra Fluoro Ethylene.
QA	:	Quality Assurance
QC	:	Quality Control
SAT	:	Site Acceptance Test
SF	:	Steri Flange
SIP	:	Sterilization in Place
SMPS	:	Switch Mode power Supply
SS	:	Stainless Steel
TC	:	Triclover
Temp.	:	Temperature
URS	:	Users Requirement Specification
VFD	:	Variable Frequency Drive
WFI	:	Water for injection



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**DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SS JACKETED MANUFACTURING  
VESSEL (4000 LITER)**

**14.0 REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			